

§ 413.230

42 CFR Ch. IV (10–1–12 Edition)

total expenditures for 2007, 2008 or 2009 to determine the year with the lowest per patient utilization.

(2) *Update of per treatment base rate to 2011.* CMS updates the per-treatment base rate under the ESRD prospective payment system in order to reflect estimated per treatment costs in 2011.

(3) *Standardization.* CMS applies a reduction factor to the per treatment base rate to reflect estimated increases resulting from the facility-level and patient-level adjustments applicable to the case as described in § 413.231 through § 413.235 of this part.

(4) *Outlier percentage.* CMS reduces the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD prospective payment system that are outlier payments as described in § 413.237 of this part.

(5) *Budget neutrality.* CMS adjusts the per treatment base rate so that the aggregate payments in 2011 are estimated to be 98 percent of the amount that would have been made under title XVIII of the Social Security Act if the ESRD prospective payment system described in section 1881(b)(14) of the Act were not implemented.

(6) *First 4 Years of the ESRD prospective payment system.* During the first 4 years of ESRD prospective payment system (January 1, 2011 to December 31, 2013), CMS adjusts the per-treatment base rate in accordance with § 413.239(d).

[75 FR 49200, Aug. 12, 2010]

§ 413.230 Determining the per treatment payment amount.

The per-treatment payment amount is the sum of:

(a) The per treatment base rate established in § 413.220, adjusted for wages as described in § 413.231, and adjusted for facility-level and patient-level characteristics described in §§ 413.232 and 413.235 of this part;

(b) Any outlier payment under § 413.237; and

(c) Any training adjustment add-on under § 414.335(b).

[75 FR 49200, Aug. 12, 2010]

§ 413.231 Adjustment for wages.

(a) CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index (established by CMS) which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located.

(b) The application of the wage index is made on the basis of the location of the ESRD facility in an urban or rural area as defined in this paragraph (b).

(1) *Urban area* means a Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB.

(2) *Rural area* means any area outside an urban area.

[75 FR 49200, Aug. 12, 2010]

§ 413.232 Low-volume adjustment.

(a) CMS adjusts the base rate for low-volume ESRD facilities, as defined in paragraph (b) of this section.

(b) *Definition of low-volume facility.* A low-volume facility is an ESRD facility that:

(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year; and

(2) Has not opened, closed, or received a new provider number due to a change in ownership in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

(c) For the purpose of determining the number of treatments under paragraph (b)(1) of this section, the number of treatments considered furnished by the ESRD facility shall equal the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both:

(1) Under common ownership with, and

(2) 25 miles or less from the ESRD facility in question.

(d) The determination under paragraph (c) of this section does not apply to an ESRD facility that was in existence and certified for Medicare participation prior January 1, 2011.

(e) Common ownership means the same individual, individuals, entity, or entities, directly, or indirectly, own 5 percent or more of each ESRD facility.

(f) Except as provided below, to receive the low-volume adjustment an ESRD facility must provide an attestation statement, by November 1st of each year preceding the payment year, to its Medicare administrative contractor that the facility has met all the criteria established in paragraphs (a), (b), (c), and (d) of this section. For calendar year 2012, the attestation must be provided by January 3, 2012.

(g) The low-volume adjustment applies only for dialysis treatments provided to adults (18 years or older).

[75 FR 49200, Aug. 12, 2010, as amended at 76 FR 70314, Nov. 10, 2011]

§413.235 Patient-level adjustments.

Adjustments to the per-treatment base rate may be made to account for variation in case-mix. These adjustments reflect patient characteristics that result in higher costs for ESRD facilities.

(a) CMS adjusts the per treatment base rate for adults to account for patient age, body surface area, low body mass index, onset of dialysis (new patient), and co-morbidities, as specified by CMS.

(b) CMS adjusts the per treatment base rate for pediatric patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act, to account for patient age and treatment modality.

(c) CMS provides a wage-adjusted add-on per treatment adjustment for home and self-dialysis training.

[75 FR 49201, Aug. 12, 2010]

§413.237 Outliers.

(a) The following definitions apply to this section.

(1) *ESRD outlier services* are the following items and services that are included in the ESRD PPS bundle: (i) ESRD-related drugs and biologicals that were or would have been, prior to

January 1, 2011, separately billable under Medicare Part B;

(ii) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

(iii) Medical/surgical supplies, including syringes, used to administer ESRD-related drugs that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and

(iv) Renal dialysis service drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, excluding ESRD-related oral-only drugs effective January 1, 2014.

(v) As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

(2) *Adult predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to an adult beneficiary by an ESRD facility.

(3) *Pediatric predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to a pediatric beneficiary by an ESRD facility.

(4) *Adult fixed dollar loss amount* is the amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to an adult beneficiary must exceed the adult predicted ESRD outlier services MAP amount to be eligible for an outlier payment.

(5) *Pediatric fixed dollar loss amount* is the amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to a pediatric beneficiary must exceed the pediatric predicted ESRD outlier services MAP amount to be eligible for an outlier payment.

(6) *Outlier Percentage*: This term has the meaning set forth in §413.220(b)(4).

(b) *Eligibility for outlier payments—(1) Adult beneficiaries*. An ESRD facility will receive an outlier payment for a treatment furnished to an adult beneficiary if the ESRD facility's per-treatment imputed MAP amount for ESRD